FOOD AND DRUG ADMINISTRATION (FDA)
RECALLS/ALERT NOTICES

1. FDA MEDICAL EQUIPMENT RECALLS AND ALERTS. The following recalls are reported in accordance with AFMLL 2-95, page CE-4, and should be treated as directed modifications in accordance with that AFMLL and AFI 41-201, Chapter 2, Section D. If you possess any of these items and have not received recall notification, you should contact the manufacturer for recall instructions. Suspension is only required for Class I items. (FOM, Mr. Dave Baker, DSN 343-7487)

CLASS I RECALLS: None.

CLASS II RECALLS:

6515NS	
MDC 13538	Sensors, Oxygen
PRODUCT	Hewlett Packard (HP) M1193A Reusable Neonatal SpO2 Sensor - used with the HP OminCare CMS patient monitor (MDC 12636), compact-configured monitors, HP CodeMaster defibrillators (MDC 11128) with an SpO2 option and Series 50XM Fetal Monitors (M1350B) (MDC 12610). The device provides continuous non-invasive measurement (via neonatal hand/foot) of arterial oxygen saturation with an HP patient monitor. Recall #Z-720-8.
CODE	HP M1193A with the following serial numbers: IN613 03281 to 03480 OR the following serial number prefixes: IN616 XXXX (XXXX=all sequence nos.) IN619 XXXX, IN620 XXXX, IN627 XXXX, IN628 XXXX, IN629 XXXX, IN630 XXXX, IN631 XXXX, IN632 XXXX, IN708 XXXX, IN720 XXXX, IN730 XXXX.
MANUFACTURER	Hewlett Packard, Boeblingen, Germany.
RECALLED BY	Hewlett-Packard Company, Medical Products Group, Andover, Massachusetts, by letter on July 14, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	1,969 units were distributed.
REASON	The device may exhibit arterial oxygen saturation measurement outside of the specified accuracy after months of use. The red light emitting diode in the sensor may degrade over time and the sensor will no longer function giving either no reading or an intermittent/variable reading in cases where normally a continuous reading would be expected.

[ ] None Present
[ ] Action Taken _____
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2. **DRUG/SUPPLY PRODUCT RECALLS AND MEDICAL INFORMATION**. The Food and Drug Administration (FDA) advises that the drug products listed below were recalled by the manufacturers or distributors concerned. The FDA has classified these recalls as follows:

CLASS I: A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.

CLASS II: A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

CLASS III: A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Most of these items are nonstandard, and the possibility exists that medical activities may have purchased them locally. There is also a possibility that some of these items have NSNs assigned and may have been reported in earlier Q.A. messages. Activities having quantities of these items on hand will immediately suspend the materiel from issue and use. CONUS activities will contact the nearest office of the respective manufacturer or distributor for disposition instructions. OVERSEAS activities will report quantities suspended to AFMLO/FOM-P no later than **16 October 98** for disposition instructions. They should include nomenclature; lot number; manufacturer; quantity suspended; strength size; requisition; and DPSC purchase order number, contract number, and stock record account number (SRAN).
(FOM-P), Bonnie Phillips, DSN (343-4170)

CLASS I RECALLS:

NSN	6515 Nonstandard
PRODUCT	Adapter and breathing circuits assembled with the adapter listed below: a) Airlife Intubation Adapter, 22 mm O.D./15 mm I.D. Both Ends; b) Airlife Isothermal Breathing Circuit, Adult Respiratory Circuit Heated, c) Airlife Isothermal Breathing Circuit, Adult Respiratory Circuit Non-Heated; d) Procedure Based Delivery System Nebulizer Kits, Custom Packaged by Allegiance Healthcare Corporation, McGaw Park, IL. Recall #Z-716/719-8.
CODE	a) Catalog No. 001820, Lot Nos. Y7H0170, Y7J1131, Y7J1132, Y7K0778, Y7K0779, Y7L0962, Y7L0963, Y7N0280, Y7N0281, Y7P0395, Y7P0394, Y7S0121, Y8A0338, Y8A0339, Y8B0427, Y8B0428, Y8C1917, Y8C1918, Y8D0452, Y8D0453, Y8E0943; b) Catalog No. 6035-H08, lot No. 8D0569, Catalog No. 6462-H08, Lot Nos. Y8B1723, Y8C0902, Y8C0991, Y8C0995, Y8C0996, Y8C0999, Y8C1000, Y8C2108, Y8C2283, Y8D1108, Y8D2290, Y8D2475, Y8D2520, F7K71771, F7K69101, F7K66501, Catalog No. 6463-H08, Lot Nos. Y8B0923, Y8B1690, Y8B1691, Y8B1692, Y8B1693, Y8B1694, Y8C1866, Y8D1277, Y8D1278, Y8D1279, F7N87301, F7K71711, F7K63521, Catalog No. 7460-HS7, Lot No. Y8C0409, Y8C0424, and F7K68661, Catalog No. 7503-HS7, Lot Nos. Y8D0558, Y8D0565, Y8D0573, and F7K68651, Catalog No. 7529-HS7, Lot Nos. Y8C0410, Y8C0421, and F7K68461, Catalog No. 7566-HS7, Lot Nos. Y8C0278, F7L76461, and F7K65961; c) Catalog No. 6687-855, Lot Nos. Y8D0692, Y8D0717, Catalog No. 6914-855, Lot Nos. Y8D0580, Y8D0581, Y8D0584, and F7K68671, Catalog No. 10122-855, Lot Nos. Y8D1195; d) Module NMK71-5682, Mfr. Dates 11/12/97, 10/16/97, and 10/2/97, Module SPC57-MASK: Mfr. Dates 3/11/98, 4/8/98, 5/12/98, and 6/15/98, Module E1456925A, All Lot Numbers, Module MC51SENEBB, All Lot Numbers prior to 7/1/98, Module MC51SENEBD, All Lot Numbers prior to 7/1/98, Module ISO514900B, All Lot Numbers, Module RES90-NHHC, All Lot Numbers.
MANUFACTURER	Allegiance Healthcare Corporation, Riverside, California.
RECALLED BY	Allegiance Healthcare Corporation, McGaw Park, Illinois, by letter on July 24,

1998. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide, Canada.

QUANTITY 8,469 cases of adapters and 123 cases of custom breathing circuits were distributed.

REASON The adapter may have a thin, plastic membrane in the center of it, with the potential

for airflow obstruction.

[ ] None Present
[ ] Action Taken _____
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CLASS II RECALLS:

NSN 6505 Nonstandard

PRODUCT Penicillin-VK, Penicillin V Potassium Powder for Oral Solution, 125 mg (200,000

U) per 5 mL, in 100 mL bottles, under the Biocraft label, Rx, used for the treatment
of mild to moderately severe infections due to penicillin-G sensitive microorganisms. Recall #D-211-8.

CODE Lot #39286 EXP 1/99.

MANUFACTURER Biocraft Laboratories, Inc., Elmwood Park, New Jersey.

RECALLED BY TEVA Pharmaceuticals USA, Inc., Sellersville, Pennsylvania, by letter on June 8,
1998. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 14,256 bottles were distributed.

REASON Stability - data may not support labeled expiration date.

[ ] None Present
[ ] Action Taken _____
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NSN 6505 Nonstandard

PRODUCT Collyrium for Fresh Eyes, Eye Wash, (borate solution). NDC #: 00008-0769-01. Recall #D-217-8.

CODE

3950841 (EXP 7/98)	3970147 (EXP 2/00)
3950980 (EXP 8/98)	3970209 (EXP 2/00)
3951149 (EXP 9/98)	3970310 (EXP 4/00)
3951148 (EXP 10/98)	3971386 (EXP 4/00)
3951215 (EXP 10/98)	3971032 (EXP 4/00)
3951216 (EXP 10/98)	3971591 (EXP 5/00)
3960020 (EXP 12/98)	3971363 (EXP 7/00)
3960039 (EXP 1/99)	3971433 (EXP 8/00)
3960040 (EXP 2/99)	3971647 (EXP 9/00)
3960382 (EXP 4/99)	3971750 (EXP 10/00)
3961288 (EXP 9/99)	3971936 (EXP 11/00)
3961765 (EXP 9/99)	3981046 (EXP 12/00)
3961509 (EXP 10/99)	3981075 (EXP 1/01)
3961988 (EXP 11/99)	3981379 (EXP 1/01)
3961913 (EXP 12/99)	

MANUFACTURER Wyeth-Ayerst Laboratories, Rouses Point, New York (responsible firm).
RECALLED BY Wyeth-Ayerst Laboratories, Richmond, Virginia, by letter dated July 15, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 1,923,379 bottles were distributed.
REASON Contamination - Product contains trace amounts of benzophenone (varnish component of bottle label).

[ ] None Present
[ ] Action Taken _____
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NSN 6505 Nonstandard
PRODUCT Nifedipine Soft Gelatin Capsules, USP, 20 mg., in 300 and 1,000 capsule bottles,

Rx antianginal. NDC #57664-873-11, NDC #57664-873-18. Recall #D-219-8.
CODE Lot numbers: 7JY06L EXP FEB 00 (300's) and 8MA18C EXP FEB 00 (1,000's).
MANUFACTURER R.P. Scherer, St. Petersburg, Florida.
RECALLED BY Caraco Pharmaceutical Laboratories, Inc., Detroit, Michigan (repacker), by telephone on June 12, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide
QUANTITY 723 300-capsule bottles and 20 1,000-capsule bottles were distributed.
REASON Some capsules may not contain any drug ingredient.

[ ] None Present
[ ] Action Taken _____
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CLASS III RECALLS:

NSN 6505 Nonstandard
PRODUCT Triamcinolone Acetonide Cream USP, 0.5%, in 15 gram tubes, Rx topical corticosteroid. NDC #49158-141-20. Recall #D-210-8.
CODE Lot numbers: M267 EXP 1/2002 and K910 EXP 6/2001.
MANUFACTURER Thames Pharmacal Company, Ronkonkoma, New York.
RECALLED BY Manufacturer, by letter mailed on July 6, 1998, followed by telephone. Firm-initiated recall ongoing.
DISTRIBUTION New York, California, Colorado, Florida, Indiana, Michigan, Ohio, Texas, Puerto Rico.
QUANTITY 28,116 units of lot M267 and 1,641 units of lot K910 were distributed.
REASON Mispackaging - Some tubes of 0.1% cream were packaged into cartons labeled as 0.5%.

[ ] None Present
[ ] Action Taken _____
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NSN 6505 Nonstandard

PRODUCT	Meperidine Hydrochloride Injection, USP, 100 mg/mL, in 20 mL vials, Rx, sterile narcotic analgesic for intramuscular, subcutaneous, or slow intravenous injection, under the Steris and Schein labels. NDC# 0402-0948-20; NDC #0364-3027-55. Recall #D-212-8.
CODE	Lot #96N790.
MANUFACTURER	Steris Laboratories, Phoenix, Arizona.
RECALLED BY	Manufacturer, by letter on June 25, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Alabama, Arkansas, Arizona, California, Georgia, Idaho, Indiana, Minnesota, Missouri, Mississippi, New York, Oregon, South Carolina, Tennessee, Texas, Wisconsin.
QUANTITY	3,237 vials were distributed.
REASON	Manufacturing deviations (unapproved batch size).
	[ ] None Present [ ] Action Taken _____ _____

NSN	6505 Nonstandard
PRODUCT	Morphine Sulfate Injection, USP, 15 mg/mL, in 20 mL multiple dose vials, Rx, a potent centrally active analgesic. NDC #0364-2366-55. Recall #D-213-8.
CODE	Lot #97B980.
MANUFACTURER	Steris Laboratories, Phoenix, Arizona.
RECALLED BY	Manufacturer, by letter on June 26, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	28,982 vials were distributed.
REASON	Manufacturing deviations (unapproved potency adjustment).
	[ ] None Present [ ] Action Taken _____ _____

NSN	6505 Nonstandard
PRODUCT	Progesterone Injection, USP, 50 mg/mL, in 10 mL multiple dose vials, Rx, under the following labels: Steris: NDC 0402-0379-10 Zenith Goldline: NDC 0182-0862- 63 Rugby: NDC 0536-7400-70 Paddock Labs: NDC 0574-0704-10 Eveready Drugs: NDC 57548-379-10 United Research Laboratories: NDC 0677-0301-21 Schein: NDC 0364-6683-54. Recall #D-214-8.
CODE	Lot 97F450 (applies to all labels).
MANUFACTURER	Steris Laboratories, Phoenix, Arizona.
RECALLED BY	Manufacturer, by letter sent on June 25, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide, Canada, Puerto Rico, South Africa.
QUANTITY	71,454 vials were distributed.
REASON	Manufacturing deviations (unapproved potency adjustment).
	[ ] None Present [ ] Action Taken _____ _____

NSN	6505 Nonstandard
PRODUCT	Cyanocobalamin Injection, USP, 1000 mcg/mL, in 30 mL multiple dose vials, Rx, sterile solution of injectable vitamin B-12, under the following labels: Steris Label: NDC 0402-0091-30 Moore Medical Label: NDC 0839-5661-36 Clint Pharmaceuticals Label: NDC 55553-091-30 United Research Laboratories Label: NDC 0677-0323-23 Zenith Goldline Label: NDC 0182-0202-66 Besse Medical Label: NDC 53614-091-30 Schein Canada Label: DIN 02229972 Keene Pharmaceuticals: NDC 0588-5215-90 Schein USA Label: NDC 0364-6651-56 The product is also packaged for export under the CYTEX LABEL. Recall #D-215-8.
CODE	Lot Number 97D690, expires 3/2000 (applies to all labels)
MANUFACTURER	Steris Laboratories, Inc., Phoenix, Arizona.
RECALLED BY	Manufacturer, by letter on June 26, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and Canada.
QUANTITY	62,635 vials were distributed.
REASON	Manufacturing deviations (unapproved potency adjustment).
	[ ] None Present [ ] Action Taken _____ _____

NSN	6505 Nonstandard
PRODUCT	Zenith Goldline brand Hydrocodone Bitartrate and Phenylpropanolamine Hydrochloride Pediatric Syrup (Hydrocordone Bitartrate 2.5mg/Phenylpropanolamine Hydrochloride 12.5 mg), in 1 pint bottles, Rx. NDC #0182-1153-40. Recall #D-216-8.
CODE	Lot numbers: 21754A and 21754F.
MANUFACTURER	Morton Grove Pharmaceuticals, Morton Grove, Indiana (contract manufacturer).
RECALLED BY	Zenith Goldline, Miami, Florida (responsible firm), by letter mailed on June 11, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	336 pints of lot 21754A and 70 pints of lot 21754F were distributed.
REASON	Mislabeling - Pediatric strength bears the NDC code for the adult strength.
	[ ] None Present [ ] Action Taken _____ _____

NSN	6505 Nonstandard
PRODUCT	Hydrocortisone 10 mg (1%) and Acetic Acid 20 mg (2%)Otic Solution USP, 10 mL size, Rx, Sterile, otic solution for treatment of infections of the external auditory canal. NDC #24208-319-10. Recall #D-218-8.
CODE	Lot Number Expiration Dates 883551 6/98 903151 8/98 933511 8/98 933521 8/98.
MANUFACTURER	Bausch and Lomb Pharmaceuticals, Inc., Tampa, Florida.

RECALLED BY	Manufacturer, by letter on May 26, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	33,643 bottles were distributed; firm estimated that 1,000 bottles remained on market at time of recall initiation.
REASON	Impurity specifications may not be met during labeled shelf life.

[ ] None Present
[ ] Action Taken _____
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NSN	6505 Nonstandard
PRODUCT	Allergy Medication Capsules (Diphenhydramine) 25 mg, OTC, packaged for American Sales, which distributes the product under the Stop & Shop and Finast labels, in 100 capsule bottles. Recall #D-221-8.
CODE	Lot Numbers: 7049878, 7049633, 7072823, 8064755, 7117566, 7118008, 7095452.
MANUFACTURER	Granutec, Inc., Largo, Florida.
RECALLED BY	Granutec, Inc., Wilson, North Carolina, by telephone on August 4, 1998, followed by letter on August 6, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	28,386 units were distributed.
REASON	Mislabeling - Product bears the tamper resistant instructions for blister packaged product not bottled product.

[ ] None Present
[ ] Action Taken _____
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